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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Butlin, et al.	
Application No.: 10/780,904	Group Art Unit: 1645
Filed: 2/17/2004	Examiner: V. A. Portner
Title: Test Methods and Devices	
Attorney Docket No.: IMIN.P-033-2	

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

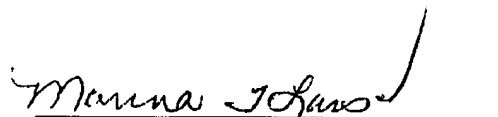
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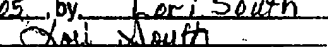
Applicants request that the references listed on form PTO 1449, which is attached, be made of record in the US Patent and Trademark Office in the file relating to the above-captioned application. Copies of the listed references should be available in the file of the parent case, Serial No.: 09/828,624.

Applicants enclose the fee for submission of this IDS. The Commissioner is authorized to charge any fees due in connection with this paper or credit any overpayment to Deposit Account No. 15-0610.

Respectfully Submitted,



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I hereby certify that the above-referenced document  
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Substitute for form 1449B/PTO		<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/780,904
		Filing Date	2/17/2004
		First Named Inventor	Butlin et al.
		Art Unit	1845
		Examiner Name	V. A. Portner
		Attorney Docket Number	IMIN.P-033-2
Sheet	2	of	3

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BARTH ET AL., Interassay differences in growth hormone measurement in acromegaly, Annals of Clinical Biochemistry, 1997, Page(s) 156-159, Volume 34, Number 2	
		BERGER ET AL., Variants of Human Chorionic Gonadotropin from Pregnant Women and Tumor Patients recognized by Monoclonal Antibodies, Journal of Clinical Endocrinology and Metabolism, 1993, Page(s) 347-351, Volume 77, Number 2	
		BIRKEN ET AL., Development and Characterization of Antibodies to a Nicked and Hyperglycosylated Form of hCG from a Choriocarcinoma Patient, Endocrinology, 1999, Page(s) 137-144, Volume 10, Number 2	
		BLETHEN ET AL., Circulating Growth Hormone Isoforms in Girls with Turner's Syndrome, Journal of Clinical Endocrinology and Metabolism, 1994, Page(s) 1439-1443, Volume 78, Number 6	
		BOGUSZEWSKI ET AL., 22-kD Growth hormone exclusion assay: a new approach to measurement of non-22kD growth hormone isoforms in human blood, European Journal of Endocrinology, 1996, Page(s) 573-582, Volume 135, Number 3	
		BURGER ET AL., The endocrinology of the menopause, Journal of steroid biochemistry and molecular biology, 1999, Page(s) 31-35, Volume 69, Number 1-6	
		CANONNE ET AL., Biological and immunochemical characterization of recombinant human thyrotrophin, Glycobiology, 1995, Page(s) 473-481, Volume 5, Number 5	
		HASHIMOTO ET AL., Construction of a specific and sensitive sandwich enzyme immunoassay for 20 kDa human growth hormone, Journal of Immunological Methods, 1998, Page(s) 77-85, Volume 221, Number 1-2	
		JANSSON ET AL., Growth hormone (GH) assays: influence of standard preparations, GH isoforms, assay characteristics, and GH-binding protein, Clinical Chemistry, 1997, Page(s) 950-956, Volume 43, Number 6-1	
		KELLY ET AL., On-line post-capillary affinity detection of immunoglobulin G subclasses and monoclonal antibody variants for capillary electrophoresis, Journal of Chromatography A, 1997, Page(s) 207-214, Volume 790	
		MATIKAINEN ET AL., Differing responses of plasma bioactive and immunoreactive follicle-stimulating hormone and luteinizing hormone to Gonadotropin-Releasing Hormone Antagonist and Agonist Treatments in Postmenopausal Women, Journal of Clinical Endocrinology, 1992, Page(s) 820-825, Volume 75, Number 3	

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		MELLADO ET AL., Characterization of Monoclonal Antibodies Specific for the Human Growth Hormone 22K and 20K Isoforms, Journal of Clinical Endocrinology and Metabolism, 1998, Page(s) 1613-1618, Volume 81, Number 4	
		OVERLIE ET AL., The endocrine transition around menopause - a five years prospective study with profiles of gonadotropines, estrogens, androgens and SHBG among healthy women, ACTA Obstetrica et gynecologica Scandinavica, 1999, Page(s) 642-647, Volume 78, Number 7	
		RAFFERTY ET AL., Difference in carbohydrate composition of FSH preparations detected with lectin-ELISA systems, Journal of Endocrinology, 1995, Page(s) 527-533, Volume 145, Number 3	
		ROGER ET AL., Heterogeneity of plasma gonadotropins. Consequences on Immunological properties of LH, Journal of Endocrinology, 1994, Page(s) 349-357, Volume 21, Number 3	
		STRASBURGER, Recognizing minorities: the 22-kD growth hormone exclusion assay (GHEA)--an invited commentary, Comment on European Journal of Endocrinology, 1996, Page(s) 536-537, Volume 135	
		WILSON ET AL., Gonadotrophin glycosylation and function (abstract only), 1990	
		ZERFAOUI ET AL., Glycosylation is the Structural Basis for /changes in Polymorphism and Immunoreactivity of Pituitary Glycoprotein....., 1996, Page(s) 749-753, Volume 34, Number 9	

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		Application Number	10/780,904
		Filing Date	2/17/2004
		First Named Inventor	Butlin et al.
		Art Unit	1645
		Examiner Name	V. A. Portner
		Attorney Docket Number	IMIN.P-033-2
Sheet	1	of	3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-5,262,518	11-16-1993	Chappel	
		US-5,674,700	10-07-1997	Maurel	
		US-5,830,880	11-03-1998	Meyerhoff et al.	
		US-5,840,857	11-24-1998	Arpaia et al.	
		US-5,914,241	06-22-1999	Valkirs	
		US-5,976,876	11-02-1999	Canfield et al.	
		US-6,087,184	07-11-2000	Magginielli et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>4</sup> - Number <sup>5</sup> - Kind Code <sup>6</sup> (if known)				
		EP 0043359 A2	01-06-1982	Pharmacia Diagnostics AB		
		WO 88/08534	11-03-1988	Unilever PLC		

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